POINT OF CARE MEDICAL DEVICE COMMUNICATION STANDARS (ISO11073/IEEE1073) IN PATIENT TELEMONITORING

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Abstract: This paper reviews the use of ISO11073/ IEEE1073 international standard in patient telemonitoring. The purpose of this family of standards is to allow interoperability between medical instrumentation devices and medical information systems. Its application in the field of telemonitoring can encourage telemedicine services and e-care, preventing failures and problems that are making difficult its spread (use problems, high costs of reconfigurations and actualizations). An application guide for the system engineer that want to apply them is proposed, showing the steps to follow, the benefits and handicaps in the standard implementation for different telemonitoring scenarios. The study also includes the conformity levels that have to be fulfilled, the main application points of the standard.

Introduction

Patient telemonitoring is one of the most frequent services in telemedicine and it allows gaining quality in (the attention given to) the patient care. It also increases the services efficiency releasing beds that may be needed for in-situ follow-ups in more critical cases. Thus, the patient will continue living at home, if it is his desire, with the benefits that it implies, comfort, favorable context, absence of trips?, etc. Telemonitoring, used in a correct way, also allows decreasing medical costs.

There are multiple telemonitoring practices: [1] home monitoring (where the patient is monitored at home and the needed parameters are sent the signals to the telemedicine system); ambulatory (that differs from the first one in that the patient uses a mobile device and can be monitored outside his house), in controlled environments as geriatric residences or a place controlled by health professionals, etc. The most advanced telemonitoring applications are applied to diabetics [2], respiratory [3], and chronic heart failures [4] patients. In most of the cases the process lies in acquisition of patient vital signs and other biomedical signals for its recording at a remote location (home or ambulatory) and their later transmission to a remote information repository where they are available for a healthcare professional review.

Some of the most widely used measuring devices are electrocardiography (ECG) monitors and pulse-oximeters (including heart rate meters), blood pressure meters, weighing scales, etc. (see Figure 1). They can be fixed but usually are wearable and wireless (incorporated in garments, bracelets, etc. by means of sensors), in order to make the process more comfortable for the patient. This group of sensors around the patient conform what is usually called a Body Area Network (BAN) or a Personal Area Network (PAN). Usually, in scenarios such as elderly patient follow-up, this PAN is completed with presence detectors or similar devices, forming a Home Area Network (HAN).

Telemonitoring services can be classified as *store & forward* and *real-time*. A store & forward service lies in the obtaining, storing and transmitting the signals for its later processing or visualization. However, if signal transmission is simultaneous to its processing or storing we are talking about real-time service. In the case of home telemonitoring the signals are usually sent using store & forward mode while in a tele-consultancy scenario it is likely to find real-time services. In this paper both modes are studied as it is shown in Figure 1:

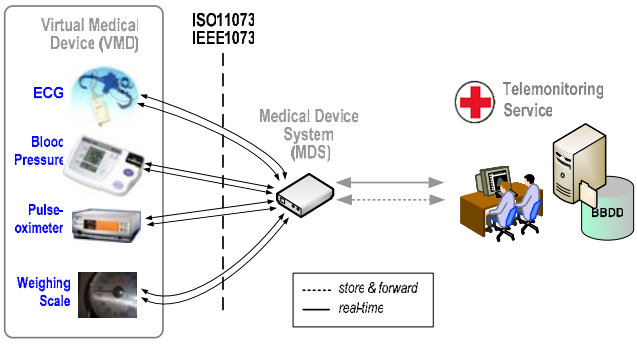

Figure 1. Home monitoring generic scenarios

- Asynchronous scenario, where a chronic or frail elderly patient is under follow-up. Here the signals are recorded, typically once a day at home, and analysed to detect trends and prevent relapses.
- Synchronous scenario, where a risk patient is telemonitored at home or at a mobile unit that transports him to a hospital after a sudden event, in an emergency situation [5].

The interoperability problem

As it was suggested before, the heterogeneity and diversity of medical devices demand to solve the problem of intercommunication between them and a central system which works as an integrated connection gateway with the telemonitoring server. The gateway is known as Medical Device System (MDS) in the ISO11073/IEEE1073 standards. The MDS may control all the monitoring devices that belong to the BAN or PAN, and monitor the patient by transmitting/receiving data and configurating and controling information. The gateway will also deal with communicating the patient network (BAN, PAN o HAN) with the telemonitoring server.

From these two links, it is in the communication between the different monitoring devices that form the patient network where some standardization can be very useful, homogenizing the interface between the devices and the MDS.

Current researches should be devoted to overcome some issues that may be preventing the widespread adoption of telemedicine:

- integration difficulties which are due to heterogeneity of medical devices. The latter is caused by the use of proprietary formats that the different manufactureres adopt. Moreover, these formats are usually not published. Then it is easy to find incompatibilities between the devices and the communication with the MDS.
- replacement problems and consequent high costs, due to single failures that imply complete system changes. One failure that makes necessary to change a device could mean lots of changes in the software and hardware that forms the system in order to maintain the communication.

Middleware systems and interoperability concepts turn up to solve these problems. The middleware technologies can be defined as the elements that allow communication in distributed systems and the tools that help to use architectures based on products from different manufacturers and multiple platforms. They provide portability (facilitate efficient interchange of vital sings and information associated to a device in all the possible clinic scenarios) and interoperability (medical application from different clinic scenarios can interchange information between devices connected to the patient).

Interoperability means *plug-and-play* systems. *Plug-and-play* means that the health professional just has to connect the device: the system detects it automatically, configures it and communicates with it and there is no need for any user interaction. The main problem about the so-called *plug-and-play* interoperability problem is the following. Without a communication standard that extends from the physical device connection through the application-language level, every interface between a medical device and any device or system with which it is to communicate must, at least, be examined to determine what physical and logical interfaces must be developed provide effective communication. The expenditure of resources will be required in virtually every case to develop and maintain the needed interface and to support the required system integration. All this confirms the need for developing open sensors and middleware components that shall allow transparent integration, plug-and-play and interoperability of non-compatible monitoring devices [6]. Thus, as it could be expected from the beginning, the use of standards seems to be an efficient way to face these problems. Standardization is necessary to make devices plug-and-play. Medical information and communication standards define information representation and exchange formats, allowing interoperability between home care devices [7]. Therefore, a unique standard is needed, but none has been completely developed by the moment.

Materials and Methods

As it was mentioned, currently a standard that solves the specific problem of the telemonitoring interoperability does not exist. The main European organization is Committee European of Normalization (CEN) [8]. Founded in 1961 by the national standards, it groups several Technical Committees (TC). Among them, the TC251 [9] works in the field of medical informatics and constitutes the only European forum for normalization of computer science applied to healthcare. It establishes international collaborations with Open System Interface (OSI), the main world organization of normalization. Moreover, there are other organizations and published standards on *middleware* telemonitoring. The most important are:

- DICOM (Digital Imaging and Communications in Medicine) [10], formed by the American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA). It is a very complete standard for medical images, extending its application between the sanitary community and the manufacturers.
- HL7 (Health Level 7) [11], founded by American manufacturers of medical equipment and accreditated by the American National Standards Institute (ANSI). It is a standard for medical messages interchange. It develops its own syntax, in the 7 levels of the protocol stack, in order to represent the information in a simple structure composed by segments and labeled fields (each one identified by its data type).
- IEEE (Institute of Electrical&Electronics Engineers), European partnership of manufacturers and institutions. It has developed the following formats:
  - VITAL [12], that defines the representation of vital signs and models for data accessing.

- INTERMED [13], that completes the VITAL model with services and communication protocols to allow interoperability between medical devices.
- IEEE1073 [14], also known as ISO11073, that groups the old Medical Information Bus (MIB) [15], for lower OSI levels, and INTERMED and VITAL for the upper levels (see Figure 2).

In summary, this ISO11073/IEEE1073 standard (1073 from here below) is a family of standards for medical devices connectivity, from physical level (cable or wireless) to abstract representation of the information and its management and exchange. The result is a unique group of standards adopted and developed by all the countries which provides interoperability, plug-and-play, transparence, easy-use and easy configuration. For all these reasons it is called Point-of-Care (PoC) medical device communication [16].

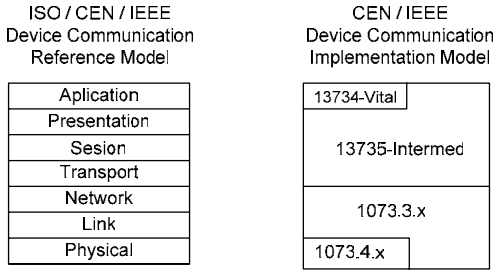

Figure 2: OSI model and ISO/IEEE11073 model

The reported work studies the family of standards ISO11073/IEEE1073 for interoperability. The main concepts of the standard are reviewed in order to map them to the two above-mentioned transmission modes scenarios, suggesting an application guide for its further implementation. It shows how to communicate and control this kind of devices following each level of the protocol stack regarding the standard (see Table 1):

- ***Highest Levels*** **(related to 1073.1.x.x)** provides definitions for information representation and interchange for medical device communication. It defines an Object Oriented Domain Information Model (DIM). It is a model represented using Universal Mark-up Language (UML) and consists of abstractions of real entities, for instance the Virtual Medical Device (VMD). A Medical Device Data Language (MDDL) based on this model is defined. It comprises common nomenclature for naming generic object patterns, syntaxes and some specific to each VMD standards (for different devices, this means specified for each VMD): ECG, pulse-oximeters, blood pressure, weighing scales monitors, etc.
  It also defines a communication services model based on the agent-manager ISO concept. Both agent and manager have a Device Communication Controller (DCC) and a Bedside Communication Controller (BCC) respectively. When two devices (an agent and a manager) try to work together, they follow four steps: 1) connection 2) association 3) configuration, and 4) operation.

Table 1. ISO11073/IEEE1073 protocols stack.

OSI Lev	ISO# 11073	IEEE# 1073	Contents *(related sources)*
7	1xxxx	1.x.x	**MDDL – Medical Device Data Language** *(related Vital-Intermed/ISO17109)*
	10101	1.1.1	MDDL – Common Nomenclature *(vital+intermed)*
	10201	1.2.1	MDDL – Domain Information Model (DIM)
	103xx	1.3.x	Virtual Medical Device (VMD) specializations: 3.1 – *Infusion device* 3.9 – *Airway flow* 3.2 – Vital signs monitor 3.10 – *Cardiac output* 3.3 – *Ventilator* 3.11 – *Capnometer* **3.4 – Pulse oximeter** 3.12 – *Hemodynamic* 3.5 – Defribillator **3.13 – *Pulmonary*** **3.6 – ECG** 3.14 – *Respirator* **3.7 – Blood Pressure** **3.15 – *Weighing scale*** 3.8 – Temperature
7-5	2xxxx	2.x.x	**MDAP - Medical Device Application Profiles** *(related Intermed/1073.2/CEN1427)*
	20101	2.1.1	MDAP - Base Standard
	20102	2.1.2	MDAP - MIB elements
	20201	2.2.1	MDAP - Polling Mode Profile
	20202	2.2.2	MDAP - Baseline Profile
	20301	2.3.1	MDAP - Optional Package, remote control
	20302	2.3.2	MDAP - Optional Package, symmetric commun.
4-1	3xxxx	3.x.x	**TPP - Transport & Physical Profiles** *(common)*
	30100	3.1.x	TPP - Connection Mode *(3.1a - Amendment 1)*
	30200	3.2.x	TPP - IrDA Based.cable connected *(3.2a - Amnd1)*
	30300	3.3.x	TPP - Infrared wireless
1	4xxxx	4.x.x	**Physical Layer Inerface Profiles**
3	5xxxx	5.x.x	**Internetworking Support**
4	6xxxx	6.x.x	**Application Gateways** *(related HL7 messages)*

- ***Intermediate Levels*** **(related to 1073.2.x.x)** defines the Medical Device Application Profiles (MDAP) distinguishing between the two transmission modes: Polling (1073.2.2.1) and Baseline (1073.2.2.2). It specifies protocols and services for communication of MDDL messages between the DCC and the BCC, for the upper three layers of the OSI model (see Figure 3). Its sections cover the basic codification and abstract syntax for the messages used by the protocols ACSE, ROSE, CMDISE, the presentation and session layer protocol; as well as the event report messages or the Protocol Data Units (PDU) sent by the devices to the host. These protocols (see Figure 4) are:
  - ACSE, which is used for the association control.
  - CMDISE (CMDIP, which is used for the basic services defined by VITAL.
  - ROSE, which provides a linkage between invoke messages and result messages (i.e., requests and responses) by means of invoke identifier.
  - The presentation layer protocol, which is used for negotiating with abstract and reference syntax.
  - The session layer protocol, for supporting ACSE.

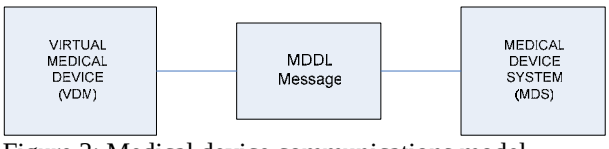

Figure 3: Medical device communications model

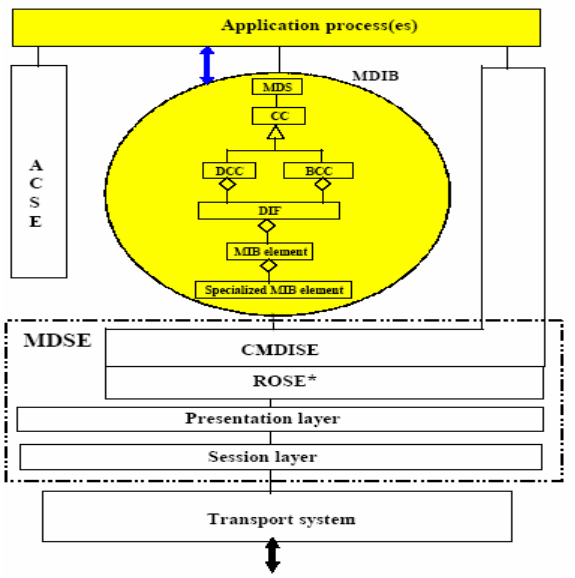

Figure 4: Medical Device Communication Stack. (Extracted from part 20101 of the Standard: Application profiles – Base Standard)

- ***Lowest Levels*** **(related to 1073.3.x.x and 1073.4.x.x)** specifies protocols and services for connection and message transport using existing international standards where possible. It also establishes the transport and physical profiles, including infrared (IrDA), cable (1073.3.2.x) or wireless (1073.3.3.x) connectivity.

Conformity levels that have to be fulfilled are specified in every case. Moreover the study includes a reference to the potentiality of some parts of the standard related to internetworking support (1073.5.x.x) and application gateways (1073.6.x.x), such as the integration with HL7 messages in medical communications that support the Electronic Patient Report (EPR). These parts are still under development.

Results

The implementation of the standard over a selected VMD strongly depends on the specific device: an ECG monitor, a pulse-oximeter, a blood pressure meter, a weighing scale, etc. because it is needed to refer to the standard part reflecting the specifics of the particular device. The VMD has to communicate with the MDS that will communicate with the hospital unit. It is in the communication between the VMD and the MDS where the 1073 standards have to be applied. As it was said there are two possible scenarios: *store-forward* and *real-time*. These two scenarios can be identified with the two different profiles that the standard uses: Polling (see Figure 5) and Baseline (see Figure 6). The application guide is made for both scenarios and for the different devices.

The guide shows the main aspects of every part of the standard family in an easy and understandable way so that the one who needs to apply a part of it (software/hardware developer) can have a simple view and understanding. From this point, the possibilities that the standard offers are shown and mapped to the given scenarios. Every OSI level is analyzed:

- *Highest Level*s (related to 1073.1.x.x): The MDDL comprises the nomenclature, which is a set of codes to name the elements in the data model, and the syntax that maps the codes to machine-processable forms. The codes that are needed: the generic ones and the ones for each scenario and device are extracted and presented. First of all the VMD model is presented for every mentioned device and the communication model as well. The agent and the manager are identified in every case. The nomenclature in this standard is primarily intended to be used in PDUs as values of fields, typically object-oriented attributes.
- *Intermediate Levels* (related to 1073.2.x.x): The PDU's fields and headers are defined through the communication stack. The guide makes a selection and a use explanation related to all the services offered by the different protocols involved (ACSE, ROSE, CMDISE, presentation and session), the syntax used and the encoding rules. The same is done for the syntax and encoding rules needed for the messages.
- *Lowest Levels* (related to 1073.3.x.x and 1073.4.x.x): For the lowest layers, and in the present scenario (a home telemonitoring environment) it is needed for the devices implied to be wireless. Using these standards the link may be possible following the 1073.3.3.x: IrDA Based/Infrared Wireless, a standard in the process of being finalized that is based on work done on the 1073.3.2 standard but that uses infrared rather than a cable; however, due to the mobility limitations of IrDA, Bluetooth could be a more appropriate technology for this scenario.

Discussion

After the proposed study, the need for Bluetooth possibilities is found. The IEEE/ISO RF wireless technologies working group (P1073.0.1.1) has been actively developing a technical report on the use of RF networks for medical devices communication. This Technical Report provides a current analysis of the issues related to the use of radio frequency (RF) wireless technologies for the transport of external communications both to and from PoC medical devices. It would be convenient to create a specific Bluetooth part of the standard. The Technical Report outlines specific exercises using detailed use case scenarios to estimate the performance, as well as compare and contrast, known technologies operating on personal area, local area, and wide area networks. Considered in these exercises are network architecture and technology, EMI/EMC, quality of service management, co-existence and interface conformance disclosure, service discovery mechanism, security, interface cost, power consumption, and technology configurability [17].

This set of standards is still in a development stage. This ends in a situation where a lot of gaps to fill can be found. Moreover its implantation is not sure yet and that gives no guarantee to manufacturers and designers to use the standard. However it seems that this has to be the standard needed for the communication between

medical devices in a home tele-care environment and initiatives like this application guide have to be taken to make real application tests and detect the problems, lacks and benefits in order to achieve its good development and implantation.

Conclusions

Since telemonitoring is getting to be an interesting upcoming application for both patients and health care providers, there is a need for communication between medical devices. In a home monitoring scenario, where one system controls and communicates with different medical devices and with a telemonitoring service provider, it seems clear that the communication has to follow a standard. That provides easiness of configuration, substitutions and reconfigurations, same rules for manufacturers and software developers and plug-and-play capacities. The integration of medical devices communication needs *plug-and-play* connectivity and interoperability so the user (patient, nurse, etc.) would be able to use it with no technical knowledge. The review gives a guide that pretends to be useful for developers as an introduction and a first implementation contact using the discussed standards. It seems to be the definitive standard for communication between medical devices in patient telemonitoring. The guide shows the steps to follow and some benefits, lacks and handicaps, and concludes that this emerging standard, currently under development, is the most appropriate for home telemonitoring PoC services communications. Furthermore, the cooperation between ISO/IEEE and the rest of the standardization organizations seems to be on the right track to achieve high interoperability between formats, medical devices and information systems.

Acknowledges

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Appendix I. Nomenclature Glossary

ACSE	Association Control Service Element
CC	Communication Controller (BCC, DCC,etc.)
CC_MIB	A unique information component of a MIB, typically an attribute of a CC (packets received or sent, errors, etc.
CMDISE	Common Medical Device Information Service Element
DIF	Device Interface
DIM	Domain Information Model
MDAP	Medical Device Application Profiles. (IEEE-1073.2).
MDC	Medical Device Communications
MDDL	Medical Device Data Language. (IEEE-1073.1)
MDIB	Medical Device Information Base
MDS	Medical Device System
MDSE	Medical Device Service Element
MIB	Management Information Base (MIB)
ROSE	Remote Operation Service Element
VMD	Virtual Medical Device